

DEPARTMENT OF HEALTH
WASHINGTON STATE BOARD OF PHARMACY
MEETING AGENDA
March 10, 2006
CenterPoint Corporate Park
Creekside Bldg #3 – 2nd Floor
20435 72nd Ave
Kent, WA 98032
253- 395-6719

CONVENE

Chair Asaad Awan convened the meeting at 9:12 a.m. on March 10, 2006. Board Members present:

George Roe, RPh
Donna Dockter, RPh
Gary Harris, RPh
Rebecca Hille, Vice-Chair
Rosemarie Duffy, RN

Absent Member:

Susan Teil-Boyer, RPh

Staff Members present:

Joyce Roper, Assistant Attorney General
Steven Saxe, Executive Director
Lisa Salmi, Deputy Executive Director
Tim Fuller, Pharmacy Consultant
Andy Mecca, Pharmacy Consultant
Grace Cheung, Chief Investigator
Richard Morrison, Pharmacist Investigator
Doreen Beebe, Program Manager

March 10, 2006

Open Meeting

Welcome to New Board Member

The meeting began with the introduction of Rosemarie Duffy. Ms. Duffy was appointed by Governor Gregoire on January 30, 2006 to serve a four year term as a public member of the Board of Pharmacy. She has been a resident in Washington State for approximately 12 years and is a nurse by profession. In her introduction she quoted Marian Wright Edelman summing up her motivation for serving her community. "Service is the rent we pay for being."

Pharmacy Intern Study Plan

Andy Mecca provided the regulatory basis for this request coming before the Board. Elise Ng, a pharmacist intern, has been unsuccessful in passing the NAPLEX. Ms. Ng is requesting that the Board approve her study plan and authorize her to re-take the exam. **MOTION:** George Roe moved that the Board accept the Pharmacy Intern study plan and approve Elise Ng to re-take the NAPLEX exam. **MOTION CARRIED.**

CONSENT AGENDA

- 1.1 Pharmacist License Application Approval
 - Thu N. Vu – Application for Nuclear Pharmacist
 - Anthony Parks – Application for Nuclear Pharmacist
- 1.2 Pharmacy & Other Firm Application Approval
 - Closed & New Pharmaceutical Firms 12/23/2005- 2/13/2006
- 1.6 Automated Drug Dispensing Device Acceptance
 - Bridgeport Pharmacy Services
 - Sunnyside Community Hospital
 - Yakima Valley Memorial Hospital
- 1.8 Board Minute Approval
 - January 26, 2006 meeting minutes

Items 1.3 –Pharmacy Technician Application Approval; 1.4- Pharmacy Technician Training Program Approval; 1.5- Collaborative Drug Therapy Agreement Acceptance; and 1.7- Sample Distribution Requests were deleted from the consent agenda. **MOTION:** George Roe moved to accept 1.1, 1.2, 1.6 and 1.8 of the consent agenda items. **MOTION CARRIED.**

REPORTS

Steve Saxe reported on the following:

Health Professions Section Four

- Judy Haenke, Program Manager and the Optometry Board is putting on a seminar next weekend with 650 participants registered for continuing education credits. The event will be held at the University of Washington. She has also been involved in the Dispensing Optician exam (given twice a year) and the North American Veterinarian licensing exam.

Personnel Issues

- Section Four has hired a temporary staff person to assist with the credentialing process during the absence of one permanent staff member. The temporary position begins this week for 3 months.
- The Veterinary Board is down two veterinarians and one public member. Interested parties may visit the Governor's web page for application information.
- The secretary's Orthotics and Prosthetics Advisory Committee also has two vacancies.
- Working with bill analysis for the Legislative Session ended 3/9.
- Doreen Beebe, Program Manager to the Board of Pharmacy and the Orthotics and Prosthetics Advisory Committee is interviewing to fill a support position.

Department of Health

- Steve Saxe has participated on the interview panel with other Department of Health staff to fill the Medical Director's position with the Washington Physicians Health Program (WPHP). Dr. Lynn Hankes, who has held the position for a number of years, plans to retire. Dr. Mick Oreskevich has been selected to fill the position. Section Four works with 3 different impaired practitioner programs: Washington Recovery Assistance for Pharmacy

Program (WRAPP), Optometry Washington Health Professional Services and WHPS.

- The department is working on a strategic plan to develop one single complaint process that will address complaints that encompass several programs. The plan is looking to develop common business practices, enhance data management, and looking at better technologies. DOH has signed a contract for a new licensing system that will support credentialing, complaints, inspection process, etc. The system will assist us in improving workforce diversity, competency and satisfaction. The strategic plan has been finalized and work will begin looking at organizational functions and structure. Each section within Health Systems Quality Assurance Division has identified the time it devotes to credentialing, complaints, compliance, inspections and board support to determine if there are opportunities to improve the functionality of the division. The Board will be updated as the process moves forward.

BOARD MEMBERS

George Roe attended the March 1st Investigators' quarterly meeting. Mr. Roe highlighted concerns expressed at the meeting regarding the need to find business license holders accountable for system related complaints. Actions against licensed personnel are often not enough to solving system issues. In some cases operating procedures and conditions which are controlled by employers may be contributing factors to dispensing errors and are controlled by employers. Mr. Roe stated that this is something that the Board should address.

ASSISTANT ATTORNEY GENERAL

Joyce Roper will be working with Steven Saxe to review the recently enacted Patriot Act, which contains language addressing methamphetamine precursors. They will be comparing the federal regulations to Washington's laws to identify where there may be differences.

CONSULTANT PHARMACIST

Tim Fuller provided an update on the Automated Devices Rules. The hearing is tentatively scheduled for June 1st. Mr. Fuller participated in an emergency response drill of the department's reception, storage and supply facility. This facility will receive drugs from the strategic national stockpile. Mr. Fuller along with Investigator Jim Doll and Deputy Director Lisa Salmi will participate in the statewide exercise planned for April 5th. The full scale exercise will include filling and sending order to various sites.

Andy Mecca updated the Board on the collaborative work being done by the Department of Health, Labor and Industries, Department of Corrections and other agencies in establishing opiate dosing guidelines. Meetings are progressing. Final guideline will be reported to the Board.

Patient counseling sign and letter explaining voluntary compliance has been posted to the Board's website and an article has been submitted for the April newsletter, which will be mailed to all pharmacists.

CHIEF INVESTIATOR

Grace Cheung reported on the following:

- Jan 31, 2006, Randy Flett provided an overview of precursor laws and rules to members of King County Sheriff, various legislature staff, city, county, state, and federal personnel from various agencies affected by methamphetamine.
- Dick Morrison, as a member of the University of Washington, School of Pharmacy Admissions Committee, has been involved in interviewing applicants to the University of Washington, School of Pharmacy.
- Stan Jeppesen and Andy Mecca are participating in a law review class designed for individuals who are studying for the MPJE. These classes are held on two Saturdays in March at the University of Washington.
- March 1-2, 2006 Investigators Meeting. Board member George Roe attended on March 1st and had a chance to meet the entire Section 4 staff at our all staff meeting. We had a full agenda of current issues and updates on procedures relating to case management.
- The investigator vacancy in Central Washington continues to pose challenges for the rest of the investigators. In addition to their own workload many investigators have been assigned Central Washington cases, practice reviews and non-routine inspections (i.e. new, relocation and remodel inspections).
- Donna Dockter tentatively accepted the invitation to attend the June 7th Investigators' meeting.

PRESENTATIONS

Cerner Corporation

Dr. Steve Ward presented Cerner Corporation's EasyScript (Sending System) and PharmNet (Pharmacy Receiving System) for Board approval.

- EasyScript solution does not currently support NCPDP script standards – it does not send prescriptions out electronically but directly to the pharmacy fax machine. In the future, should the system transmit prescriptions other than via fax, Cerner will request an amended approval from the Board.

MOTION: George Roe moved to approve the electronic prescription transmission and receiving systems by Cerner Corp with the stipulation that it documents chronic conditions and remove the brackets on the refill-prescription **MOTION CARRIED.**

PDX Inc.

Ben Loy, Senior Vice-President of PDX Inc. presented their eRx Network (Gateway System) and Pharmacy PDX Retail Pharmacy Management System (Pharmacy Receiving System) to the Board for approval. **MOTION:** George Roe moved to approve the electronic prescription transmission and gateway systems by PDX Inc. once the system shows "Dispense as Written" and the physician's DEA # on screen. **MOTION CARRIED.**

LSS Data Systems

Ken Carlson, CEO and Chief Technology Office of LSS Data System presented their electronic prescription transmission system (Sending) to the Board for approval. **MOTION:** George Roe moved to accept LSS Data Systems. **MOTION CARRIED.**

DISCUSSION

Update 2006 Legislative Session

Steve Saxe recognized Rebecca Hille for her participation in the Monday “meet me” calls, which provided the department an opportunity to receive input from representative of all Boards, Commissions, and Advisory Committees on 2006 multi-profession bills.

Mr. Saxe provided a summary of legislative bills of interest to the Board and Section Four.

HB2292 Healthcare Liability Reform – Patient safety malpractice bill – legible prescription clause, which requires prescriptions to be hand printed, type written or electronically generated Signed by Governor. Effective 90 days after end of session.

ESB6194 Multicultural Education for Healthcare Professionals - Requires multicultural education to be incorporated in the curriculum of the professional educational programs within the state. The Department of Health will be charged with developing ongoing cultural diversity education. This bill also looks into disparity in access to healthcare for different cultural groups. This bill passed and is waiting to be signed by the Governor.

SHB2974 Health Professions Discipline – Mandatory reporting of findings of unprofessional conduct. A section of this bill provides that the disciplinary history is given to the boards as it looks at authorizing investigations. This legislation emphasizes public safety. The Washington State Patrol will report any violations that they may be aware of to any disciplinary boards. There are concerns that this bill did not address property crimes, which is an issue when dealing with vulnerable adults. Also related to this bill is a decision package for funding to do national databank checks for all applicants. In addition, a provision of this bill authorizes a summary suspension of the license status in Washington pending retribution for actions taken by another state. This bill passed and is waiting to be signed by the Governor.

HB1850 Retire Volunteer Medical Workers’ License – creates a retired volunteer medical license – up to 10 years out of practice. The Department of Health is charged with establishing continuing competency requirements. This license is for working in emergency situations. The bill also addresses liability issues for the retired worker. This bill passed and is waiting to be signed by the Governor.

SB6193 Surveys of Health Professions Work Force Supply and Demographics. This bill passed.

Optometry Licensing – eliminating tiered licenses for all Optometrist by 2011. All optometrist must get have completed the training and licensure to prescribe oral drugs and epinephrine. This bill requires rule making. New applicants in 2007 must meet new credentialing level. This bill passed.

SB6591 Expanding provisions relating to wholesale distribution of dangerous drugs. This bill did not pass. A significant amount of work and meetings went into this bill. There were issues around pedigree and concerns raised regarding penalties. Look for this bill to return in 2007.

HB332 Controlled Substances Prescription Monitoring Program. Representative Hinkle dropped this bill shortly before the session ended. The Board will be providing comments to prepare for next session. The department had a grant last year and did significant stakeholder work and wrote draft rule language.

Health Systems Quality Assurance division reviewed 134 bills. The office of Health Professions Quality Assurance was lead on 98 and assigned as support on 36 bills.

Engrossed Substitute House Bill 2266

The law which was passed in 2005, effective January 1, 2006, requires the Board of Pharmacy to form a task force or work group to assess the effectiveness of methamphetamine precursor retail logs. The group will evaluate:

- Whether the log or other means of recording the transactions is an effective law enforcement tool?
- What information is needed to make logs or other means of recording a transaction useful as a deterrent to criminal activity?
- What is the most effective and least intrusive method of obtaining, recording, and storing the log or other electronic data?
- How long the information should be maintained?
- How can the information be most effectively transmitted to law enforcement and the Board of Pharmacy?

The members of the Task force include representation from the Washington State Association of Sheriffs and Police Chiefs, Washington State Patrol, Washington Association of Prosecuting Attorneys, Attorney General's Office, two representatives from the retail industry and a Board of Pharmacy member. A letter will be going out soon to invite retail folks to come to the table to select 2 representatives. We also need to identify a representative from the Board. It is anticipated that the task force will meet for 8 half-day meetings.

MOTION: Rebecca Hille moved to appoint Donna Dockter with her valuable retail background to the Meth Task Force as a representative of the Board. **MOTION CARRIED.**

University of Utah School on Alcoholism and other Drug Dependencies

Due to schedule conflicts Rosemarie Duffy and Gary Harris are unable to attend. **MOTION:** Rebecca Hille moved Board staff appoint two appropriate staff members to attend the Utah training. **MOTION CARRIED.**

Northwest Women's Law Center & Planned Parenthood

Steven Saxe reminded the Board that representatives from Northwest Women's Law Center and Planned Parenthood requested in January to present to the Board their views following the Washington State Pharmacy Association's presentation on a Pharmacist's "Conscience Clause." Mr. Saxe went on to say that this is just one step in the rules process. The rule making process initiated by the Board in January will consist of stakeholder meetings held in various locations throughout the state and are scheduled to begin this spring. The Board will then determine whether rules are needed. If rules are necessary, draft language will be written and additional public comment received. This is a very open process.

Washington has been a leader – first in the country where pharmacists with a collaborative agreement can prescribe and dispense emergency contraception. Washington has the longest running pharmacist emergency contraception training program. Training is available for pharmacist through the American Pharmacy Association and the Washington Pharmacy Association (WSPA) and included as part of the curriculum for pharmacy students.

Steven Saxe reiterated that the Board staff advises pharmacists to be proactive by working with their employers and colleagues to ensure patients receive timely and convenient patient care.

The following is a summary of the presentation made to the Board by Nancy Sapiro, representing the NW Women's Law Center; Roberta Riley and Amy Luftig representing Planned Parenthood Presentation.

The presenters provided a brief overview of the legal landscape in Washington and why they feel that pharmacist have a greater responsibility to their patients under Washington law than the position reported in the WSPA's position presented at the January meeting. Ms. Sapiro stated that while they think that WSPA's proposal is viable in some respects they feel it is an inadequate response to the issue of pharmacist's refusals in this state.

They acknowledged that the vast majority of pharmacists in this state take their ethical and legal responsibility very seriously and that they are committed to protect the patients' safety and timely access to needed medications. They went on to say, pharmacists in this state are refusing to fill prescriptions and particularly refusing to fill prescriptions for birth control. In so doing they are creating a significant new threat to women's reproductive healthcare. The impact of these refusals is not simply minor inconveniences they pose significant barriers to necessary health care for women. These negative impacts are greatest for those with limited access to alternative pharmacies.

Reasons to fill legally prescribed medications:

- Professional standards of conduct
- National Pharmacist Codes of Ethics - requires pharmacist to avoid actions that compromise the dedication to the best interest of their patients.
- Washington laws
 - Duty to fill – pharmacy practice
 - RCW 9.02.100 Reproductive Privacy Act - that an individual had a fundamental right to choose birth control and that the state can not discriminate in a way that inhibits an individual's ability to exercise that right.
 - 1978 US Supreme Court noted that laws can not interfere with religious belief/opinions, the constitution protects these individual beliefs; however, laws may regulate our actions.

Reasons not to fill legally prescribed medications:

- Professional judgment
 - Forgery
 - Contraindications

Amy Luftig highlighted trends in the nations and gave four examples from Washington State of pharmacist refusing to fill prescriptions for antibiotics, syringes, prenatal vitamins and ECP citing religious or implying other biases. Ms. Luftig stated that these examples pose a direct health risk to the client and are not limited to emergency contraception.

National Trends

- Other states and pharmacy boards summarily reject pharmacists' right to refuse in favor of patient protection
- Wyoming and Nevada Boards of Pharmacy adopted a proposal that pharmacists can refuse only on the basis of unlawful prescription or contraindications.

- North Carolina Board released a policy stating it is unacceptable for pharmacist to impose their moral or ethical beliefs on their patients they serve.
- Governor Jim Doyle of Wisconsin stated regarding a similar bill proposal - it is hard enough for many people to get the healthcare they need.

They acknowledged that the WSPA's position paper recognizes the foremost responsibility of a pharmacist is to provide pharmaceutical care to their patients. They strongly disagreed that in those instances when a pharmacist's personal beliefs conflicts with their professional responsibilities the pharmacist's has the right to refuse to fill. A referral is not a minor inconvenience for many women who live in towns with only one pharmacy or have to go to another town or across town. This is especially compelling when you think of emergency contraception where the efficacy of the drug is decreasing.

Ms. Sapiro, Ms Luftig and Ms. Riley urged the Board to follow their colleagues in other states and reach the same conclusion. They asked the Board to move forward with a policy that will protect the health of all Washington residents to ensure that no one is denied safe and legal prescriptions in this state because of an individual's personal beliefs. Without imposing an undue burden on the employer, the employer should attempt to accommodate the employee. Pharmacies can accommodate the religious refusal of pharmacist while protecting a patient's rights if and only if the patient's care is not disrupted or delayed in anyway.

Comments from the Audience

There were approximately eighty persons in attendance. Twenty-one individuals provided their input on the issue and their perspective of the presentation by the NW Women's Law Center and Planned Parenthood. Eighteen supported a "conscientious clause", three opposed. Speakers included representation from healthcare practitioners, lawyers, political affiliations, pro-choice activist groups, religious affiliations, pharmacy students and concerned citizens.

The Board acknowledges the passion of each speaker and appreciates the opportunity to consider their input. The following is a summary of the comments addressed to the Board regarding a pharmacist's right to exercise their conscience.

- RCW 48.43.065(2) - no individual healthcare provider may be required to participate in a specific service if they object for reasons of conscience or religion.
- RCW 9.02.100 - Reproductive Privacy Act
- There are over 7000 pharmacist licensed in Washington – no access problem.
- Abortifacient verses emergency contraception (prevents implantation verse prevents ovulation)
- To be required to refer a patient elsewhere would not honor the pharmacist's conscience, but rather a partner in the process.
- Planned Parenthood has a financial interest in Plan B.
- The Hippocratic Oath – states above all do no harm.
- According to the NotToLate webpage there are 515 providers of emergency contraception in Washington, of which 87 providers are in the 509 area code.
- Employers provide reasonable accommodations to allow a pharmacist's to exercise conscientious objection.
- Washington State law provides for women's rights to reproductive choices
- Even if I choose not to fill, I recognize that the prescriptions belong to the patient.

- The 1st Amendment of the Bill of Rights states in part Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof...
- The name emergency contraception is a misnomer. There is no emergency. The drug is effective if taken within 120 hours after unprotected intercourse.
- Recognition of the civil rights of pharmacist does not infringe on the rights of patients.
- There is no crisis of availability or access. Emergency contraception is available through mail-order, internet, Planned Parenthood Health Center.
- Other professionals such as physicians, lawyers, nurses, etc. have the right not to participate in the termination of a pregnancy. RCW 9.02.150
- Checks and balances are a good thing when it comes to critical matters of life and death.
- State law defines that pregnancy begins with the implantation of the fertilized ovum on the uterine wall.
- Exercising one's conscience is not unrestricted.
- What about drugs prescribed for assisted suicide?

Draft Response to Interested Parties

The letter drafted to respond to the number of letters regarding a pharmacist's right to exercise conscientious objection was distributed to the Board. Steven Saxe asked the Board for its input.

MOTION: Rebecca Hille moved to remove emergency contraception from paragraph 2 and remove paragraph 3 entirely. **MOTION CARRIED.**

MOTION: George Roe moved that item 4.4 GMAP Presentation, 4.5 Operating Agreement, 4.8 Notice of Correction & Stipulations to Informal Disposition, and 4.9 Future Board Agenda be postponed until a future meeting. **MOTION CARRIES.**

Adjournment

There being no further business, the Board adjourned at 4:00 p.m. They will meet again on April 20-21, 2006 in Yakima, Washington.

Respectfully Submitted by:

Doreen E. Beebe, Program Manager

Approved on April 20, 2006

*Dr. Asaad Awan, Chair
Board of Pharmacy*